

**Georgia State University
Mark Chaffin Center for Healthy Development
School of Public Health
Informed Consent**

Title: Mom & Baby Net

Principal Investigator: Kathleen Baggett, Ph.D.

Sponsor: NIH/NICHD

I. PURPOSE

You are invited to participate in a research study. The purpose of this study is to learn about how it works to put two programs together. One program is for helping parents learn how to change thoughts and actions to help themselves feel better. The other program helps parents learn ways to help their babies' development. We want to find out if putting these two programs together and giving moms an iPhone to complete the program helps moms and babies. You are invited to be a part of the study because you have said that you have been feeling down and you want to help your baby grow in a healthy way. A total number of 180 moms will be recruited for this study. The study will take about 26 hours of your time over up to 12 months.

II. PROCEDURES

If you decide to participate, you will be asked to complete the following:

1) Visit 1 (1.5 hours): A research team member will visit you in your home to read the consent form. You will follow along on your own copy. The team member will ask you to say what you understand about the project and to ask questions. The research staff will answer your questions. If you decide to be in the study, you will use an iPad to answer questions about you and your baby. Questions can be read aloud to you on the iPad while you wear ear phones. If you don't want to answer a question, you can skip it. The research staff will record a 10-minute video of you and your baby. The video will be divided into two parts. The first part will be playing with your baby as usual at home. The second part will be looking at a book with your baby. You can ask for the video to be stopped at any time.

2) Visit 2 (1.5 hours): During this visit, you will be given an iPhone. You will receive one of two parent programs. Both programs are set up the same way, but have different information. We want to find out which program helps parents and babies the most. We will show you how to use the phone. You don't have to know how to use an iPhone before you start the program.

Also during this visit you will use your iPhone to go to one of two parent program apps. A research staff person will show you how to use the program. You have an equal chance of being in either program. This will help us find out if one program works better than the other. Each program has the same number of sessions and the main activities

are the same as described below under weekly program activities.

3) Weekly Program Activities (14 sessions, 1.5 hours each): You will use the iPhone to go through one of the two parent programs. Each program has 14 weekly sessions. You will have up to 8 months to complete the app program to make sure you have plenty of time to complete it. We understand that sometimes things come up and you may not be able work in the program each week.

Each of the 14 sessions will take about an hour to complete. You do not have to complete the activities all at the same time. Instead you can go through each session at your own speed. You can stop and start again when it's best for you. After each session you will have a 30 minute call with your coach.

During each session you will do the following:

- Listen to parent information
- Watch videos of other moms and babies
- Make a plan to use the skills for yourself and your baby
- Make a video of you and your baby
- Have a weekly call with your coach on your iPhone to talk about what you are learning in the program and watch the video that you made with your baby. Calls are recorded for quality assurance.
- Tell us what you think about the program session

During some sessions you will answer questions about how you are feeling. In between sessions, your coach may send messages to check in.

4) Visit 3 (1.5 hours): After you finish the iPhone program, we will schedule a time in your home to answer questions and make a video of you and your baby. You will keep the iPhone (valued at \$350) at the end of this meeting.

5) 3 Follow-Up Assessments (15 minutes each): At 1, 3, and 6 months after the program, you will use your iPhone to answer questions about parenting and to record a 5-minute video to be sent to the project.

Mom who are not making progress and cannot be reached after 2 weeks will be sent a letter to confirm their continued participation. All participants will be given the opportunity to complete the post-assessment.

III. Risks

There are possible risks to being involved in any research study. Though we believe these risks to be small, we want you to know what they are and the steps we take to protect against them.

1) You will be asked personal information about you and your baby. You might feel

uncomfortable answering questions about your child or making a video. If you are uncomfortable, you may talk about your concerns with the project staff.

2) Everything on the Internet is at risk to be seen by someone unexpected. There is a chance that someone who is not supposed to see information about you will accidentally see it. On our part, any information you give us will not have your name on it, but will be marked by a number instead, and the staff has been trained to keep information private. Although recordings will be labeled by a number, videos are facially identifiable, and someone who views them could recognize you or your baby.

3) We will not give information to anyone unless you give us signed permission or unless we observe or you tell us of a concern about: 1) abuse, neglect, or endangerment of a child or elder; or 2) that anyone is in immediate danger of seriously hurting himself/herself or someone else. Such reports will be made, with or without your consent, as required by the law and for the safety of all persons, to the appropriate authorities. If there is a concern about child safety, Child Protection services are called as required by law. If there is concern about the immediate safety of an adult emergency medical services are contacted, as required by law. If any person threatens to harm another, the police are called, as required by law.

4) Because you will have an iPhone with Internet access, there is the chance that you or others will be able to see sites that you don't want to. It is your responsibility to use your iPhone safely. We will show you how to lock and use a password to keep your phone safe and to store your phone safely. Don't give your password to anyone.

IV. Benefits

Participation in this study may benefit you personally. Some parents like learning about their baby's development. They sometimes say that they feel better and their relationship with their baby has gotten better. Overall, we hope to gain information to help us make the program better for other mothers and babies in the future.

V. Compensation

You will have the iPhone to use at no cost to you during the study. The cost of the phone is \$350 for the research project to buy it. If the phone breaks, we will have it fixed or replaced. If your phone is stolen, we will file a police report and remotely lock and wipe your phone. If your phone is lost, we will remotely lock and wipe the phone. We may give you a new phone to finish the study after we talk about keeping the phone safe. If you choose to stop being in the study, a member of the research team will retrieve your phone.

You will keep the phone when you complete study activities through visit 3 but we will not continue to pay for phone service. You can use the phone's wireless Internet anywhere that you have Wi-Fi (for example, many coffee shops, parks, libraries, and schools).

VI. Voluntary Participation and Withdrawal

Participation in research is voluntary. You do not have to be in this study. If you decide to be in the study and change your mind, you can stop being in the study at any time. You may skip questions or stop being in the study at any time. Whatever you decide, you will not lose any benefits or services that you receive. However, you will have to return the iPhone.

VII. Confidentiality

We will keep your records private as allowed by law. Dr. Baggett and her research team will have access to the information you provide. Information may also be shared with those who make sure the study is done correctly (GSU Institutional Review Board, the Office for Human Research Protection, NIH). We will use a study number rather than your name on all study records. A code sheet will be used to identify research participants. The code sheet will be stored in a password-protected file on a locked computer in a locked office and is destroyed at the end of the study. All information uploaded on the iPhone app is secured and the Internet connections are secured. We use the same approach as banks and online stores (e.g. Amazon.com). Your coach and your coach's supervisor are the only people who will see the weekly session videos that you make and send to your coach. All video recordings are stored on a secure server accessible only by the project director and assigned staff using a special code. You can also ask that the video be deleted after it is sent. Five years after the study is finished, all videos and recordings will be deleted.

Your name and other facts that might identify you will not be used when we present this study or publish its results. The findings will be summarized and reported in group form. You will not be identified personally.

A description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

VIII. Contact Person

Contact Dr. Baggett at kbaggett@gsu.edu or 404-413-1571 if you have questions, concerns, or complaints about this study. You can also call if you think you have been harmed by the study. Contact Susan Vogtner in the Georgia State University Office of Research Integrity at 404-403-3513 or svogtner1@gsu.edu if you want to talk to someone who is not part of the study team. You can talk about questions, concerns, offer input, obtain information or suggestions about the study. You can also call Susan Vogtner if you have questions or concerns about your rights in this study.

XI. Copy of Consent Form to Participant

We will give you a copy of this consent form to keep.

If you are at least 18 years old and you want your and your baby to be included in the study, sign below.

Print Participant's Name

Child's Name

Participant's Signature

Date

Principal Investigator or Researcher Obtaining Consent

Date